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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,315	10/24/2005	Shin-Jen Shiao	JA-SHIAO-US-1	2698

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EXAMINER	
THOMAS, TIMOTHY P	
ART UNIT	PAPER NUMBER
1614	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/554,315	SHIAO, SHIN-JEN	
	Examiner	Art Unit	
	Timothy P. Thomas	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-63* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *25-63* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 25-33, 56-62, drawn to a drug composition containing edible acid and/or acidic salt and a pharmaceutically acceptable compound.

Group II, claim(s) 34-39, 55 (in part; when a product of any one of claims 47-50) drawn to a health care food.

Group III, claim(s) 55 (in part; when a product of any one of claims 51-54), drawn to allergy-free clothing.

Group IV, claim(s) 47-50, drawn to a method of preparing protein-denatured food.

Group V, claim(s) 51-54, drawn to a method of producing allergy free clothing.

Group VI, claim(s) 63, drawn to a method of treating or alleviating hypersensitivity diseases.

Note 1: Claims 40-41, drawn to "use" claims, have not been placed with any of the above groups, since they may be interpreted in different ways; i.e., the claims may be interpreted as drawn to any of the following:

A drug composition;

A method to lower the humor pH; or

A method to treat or alleviate hypersensitivity diseases.

Upon amendment to clearly reflect applicant's intent, the claims may be rejoined to Group I or VI (or placed into another Group VII)

Note 2: Claims 42-46, drawn to "use" claims, have not been placed with any of the above groups, since they may be interpreted in different ways; i.e., the claims may be interpreted as drawn to any of the following:

A health food;

A method to lower the humor pH; or

A method to treat or alleviate hypersensitivity diseases.

Upon amendment to clearly reflect applicant's intent, the claims may be rejoined to Group II or VI (or placed into a Group VII)

2. The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking groups I-VI is an edible acid and/or acidic salt in the presence of another compound. Ohashi, et al. (US 6,297,244 B1) teaches a stable drug composition comprised of AS-3201 and at least one acidic substance, such as ascorbic acid, citric acid, tartaric acid, lactic acid, maleic acid, malic acid or phosphoric acid (edible acids; abstract). Since the prior art teaches the technical feature the invention lacks novelty. Therefore the technical feature linking the inventions of groups I-VI does not constitute a special technical feature as defined by PCT Rule 13.2 as it does not define a contribution over the prior art. Accordingly, Groups I-VI are not so linked by the same or a corresponding special technical feature as to form a single inventive concept.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

(i) If Group I is elected applicant must elect one from (ia)-(ic):

(ia) a composition containing an edible acid and/or acidic salt and a pharmaceutically acceptable compound that lowers pH (claim 25); if elected applicant must elect:

(ia1) a single disclosed edible acid specie or a single disclosed acid salt specie or a disclosed combination of acid and salt species (from species in claim 26); and

(ia2) a single disclosed pharmaceutically acceptable compound specie that lowers pH;

(ib) a composition containing an edible acid and/or acidic salt (that lowers pH) and a single drug (claims 56-58, 60-61);); if elected applicant must elect:

(ib1) a single disclosed edible acid specie or a single disclosed acid salt specie or a disclosed combination of acid and salt species (from species in claim 26); and

(ib2) a single disclosed drug subgenus (from species in claims 56-58, 60-61); and

(ib3) a single disclosed drug specie (e.g., diphenhydramine, Table 3, specification);

or

(ic) a composition containing an edible acid and/or acidic salt (that lowers pH) and two different drugs (claim 59); if elected applicant must elect:

(ic1) a single disclosed edible acid specie or a single disclosed acid salt specie or a disclosed combination of acid and salt species (from species in claim 26); and

(ic2) two disclosed drug subgenuses (from species in claims 56-58, 60-61); and

(ic3) two disclosed drug species (e.g., diphenhydramine, Table 3, specification);

(ii) If Group II is elected applicant must elect one from (iia)-(iib):

(iia) a composition containing an edible acid and/or acidic salt and a food acceptable compound that lowers pH (claim 34); if elected applicant must elect:

(iia1) a single disclosed edible acid specie or a single disclosed acid salt specie or a disclosed combination of acid and salt species (from species in claim 35); and

(iia2) a single disclosed food acceptable compound specie that lowers pH;

or

(iib) a composition containing an edible acid and/or acidic salt (that lowers pH) and a food (claims 36-37, 39); if elected applicant must elect:

(iib1) a single disclosed edible acid specie or a single disclosed acid salt specie or a disclosed combination of acid and salt species (from species in claim 35); and

(iib2) a single disclosed food or drink specie (from species in claims 36-37, 39);

or

(iii) If any of Groups III-VI is elected applicant must elect:

(iia) a single disclosed edible acid specie or a single disclosed acid salt specie or a disclosed combination of acid and salt species (from species in claims 49, or 53);

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

4. The claims are deemed to correspond to the species listed above in the following manner:

(i) Claims 25-33, 56-62

(ii) Claims 34-39, 55

(iii) Claims 47-55, 63

The following claim(s) are generic: all claims are generic for a edible acid and/or acidic salt.

5. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: As described above the technical feature linking the acid species lacks novelty over the prior art; the other components are mutually exclusive. Therefore the species are not so linked by the same or a corresponding technical feature as to form a single inventive concept.

6. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not

distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP

§ 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy P. Thomas whose telephone number is (571) 272-8994. The examiner can normally be reached on Monday-Thursday 6:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/TPT/
Timothy P. Thomas
Patent Examiner

Ardin H. Marschel 8/24/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER